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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,898

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Alexis Parenty

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
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PHILADELPHIA, PA 19103-2307

EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

07/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,898	Applicant(s) PARENTY ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-25, 28, 29 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-16, 18-25, 28, 29, 32-38 and 42 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on June 15, 2010, the applicants have elected group I with traverse for further prosecution.

Response to Arguments

2. Applicant's arguments filed on June 15, 2010 have been fully considered but they are not persuasive regarding restriction requirement. The examiner does not agree with the applicants arguments that compounds of formulae A, Ai and Aii have common core. The compounds of formula A can be bicyclic ring system containing three N atoms as heteroatoms while compounds of formula Ai can be bicyclic ring system containing two N atoms as heteroatoms. On the other hand, the compounds of formula Aii are tetracyclic ring system. Thus, there is no common core present even among these

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three formulae. Thus, restriction requirement as indicated is proper and thereby made final.

3. Claims 1-16, 18-25, 28, 29 and 32-42 are pending in the application. Claims 7-11 and 39-41 are withdrawn from further consideration as being drawn to non-elected inventions.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating ovarian cancer, does not reasonably provide enablement for treating every known cancer, inflammatory disease or protozoal infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed: Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the

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prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, state of the prior art, unpredictability and the breadth of claims.

The instant specification teaches inhibitory effect of instant compounds in ovarian cancer cell lines in vitro as shown in table on pages 48-53. Based on these teachings, the instant compounds will have utility for treating ovarian cancer. There is no teaching or guidance present either in the specification or prior art that compounds having inhibitory effect in ovarian cell line in vitro are well known to have therapeutic utility for treating every known cancer, inflammatory disease and protozoal infection. There are no working examples present showing efficacy of instant compounds in known animal models or in vitro cell lines of every known cancer, inflammatory disease and protozoal infection. The instant compounds of formula Aii encompasses hundreds of thousands of compounds based on the values of variables R6-R16 and therefore, in absence of such teachings, guidance and absence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models or in vitro cell lines of every known cancer, inflammatory disease and protozoal infection and hence their utility for treating every known cancer, inflammatory disease and protozoal infection.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-5, 12-16, 18-25, 28, 32-38 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, last paragraph on page 4, the definitions of aromatic substituents defined as H, Halogens, OH etc. are vague and indefinite. The term --- aromatic --- means unsaturated ring. Therefore, it is not clear how H, OH or halogen etc. can represent aromatic substituent.

In claim 28, it is not clear which condition is being treated by the instant compounds?

In claim 36, formulae Ai and Aii are mentioned but are not present in the claim. Furthermore, phenanthridinium compound of formula Ai is mentioned (see last three lines). However, there is no phenanthrinium compound of formula Ai present in the claim. An appropriate correction is required.

9. Claims 1-6, 12-16, 18-25, 28, 29, 32-38 and 42 are objected for containing non-elected subject matter.

Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds directed to the elected subject matter are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the art, Parenty (J. Org. Chem., cited on applicants form 1449) discloses compounds in table 1 (see page 5936) which do anticipate the instant claims. However, this publication does

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not constitute a prior art reference since it was published on web (Aug. 6, 2004) much later than the effective filing date (Nov. 26, 2003) of the instant application.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625

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